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| 10/050,307 | 01/16/2002 | Hosheng Tu | T&Q-67 | 2192 |
| 7590 | 06/16/2004 | | | |
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| Newport Coast, CA 92657 | | | | |
| | | | EXAMINER | |
| | | | KREMER, MATTHEW J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/050,307

Applicant(s)

TU ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-11,16 and 18-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 and 18-30 is/are allowed.
- 6) ☒ Claim(s) 1 and 6-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Non-Final Rejection

1. The Examiner has presented rejections for claims that were previously indicated as allowable. Since the Applicant's amendment did not necessitate the new ground(s) of rejection presented in this Office action, **THIS ACTION IS MADE NON-FINAL.**

Terminal Disclaimer

2. The terminal disclaimer filed on 4/2/2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Application No. 10/011062 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

3. Claim 16 is objected to because of the following informalities. The Applicant includes the limitation "comparing said first impedance-temperature derivative at a tissue temperature of interest with reference first impedance-temperature derivative of the normal tissue at said tissue temperature of interest adapted for tissue differentiation," which is a method step even though an apparatus is being claimed. Since the limitation does not further limit the structure of the claimed apparatus, the Examiner has not given this limitation any patentable weight.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2002/0026127 to Balbierz et al. It is noted that the limitation “for differentiating in a given area of tissue a tumorous tissue from a normal tissue” is merely “intended use” language, which cannot be relied upon to define over Balbierz et al., since Balbierz et al. discloses all of the claimed elements and their recited relationships.

See Ex parte Masham 2 USPQ 2nd 1647. Balbierz et al. teaches an apparatus with sensors for measuring impedance and temperature (paragraph 0091 to Balbierz et al.) and a means for effecting tissue temperature by energy source 20 (paragraph 0098 of Balbierz et al.). It is noted that the limitation "for differentiating in a given area of tissue a tumorous tissue from a normal tissue" is merely "intended use" language, which cannot be relied upon to define over Balbierz et al., since Balbierz et al. discloses all of the claimed elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. It is further noted that the limitation "comparing said measured tissue impedance over at least a portion of the range of tissue temperatures with reference tissue impedance of the normal tissue adapted for tissue differentiation, wherein said reference tissue impedance is measured over said range of tissue temperatures" was not given any patentable weight since the limitation does not add any structural limitation to the apparatus claim.

6. Claims 1, 6, and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,719,755 to Sliwa et al. (Sliwa). In regard to claim 1, it is noted that the limitation "for differentiating in a given area of tissue a tumorous tissue from a normal tissue" is merely "intended use" language, which cannot be relied upon to define over Sliwa, since Sliwa discloses all of the claimed elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. Sliwa teaches an apparatus with sensors for measuring impedance and temperature (column 14, lines 58-64 of Sliwa.) and a means for effecting tissue temperature (column 26, lines 38-42 of Sliwa). It is noted that the

limitation "for differentiating in a given area of tissue a tumorous tissue from a normal tissue" is merely "intended use" language, which cannot be relied upon to define over Sliwa, since Sliwa discloses all of the claimed elements and their recited relationships. See *Ex parte Masham 2 USPQ 2nd 1647*. It is further noted that the limitation "comparing said measured tissue impedance over at least a portion of the range of tissue temperatures with reference tissue impedance of the normal tissue adapted for tissue differentiation, wherein said reference tissue impedance is measured over said range of tissue temperatures" was not given any patentable weight since the limitation does not add any structural limitation to the apparatus claim. In regard to claim 6, the temperature range is 0-80°C, which includes 20-38°C. (column 26, lines 38-42 of Sliwa). In regard to claim 9, temperature sensors are disclosed. (column 26, lines 38-42 of Sliwa). In regard to claims 10-11, radio-frequency heating (column 14, lines 61-64 of Sliwa) and circulating fluid for cooling (column 14, lines 42-45 of Sliwa).

7. Claims 1 and 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,741,895 to Gafni et al. (Gafni). In regard to claim 1, it is noted that the limitation "for differentiating in a given area of tissue a tumorous tissue from a normal tissue" is merely "intended use" language, which cannot be relied upon to define over Gafni, since Gafni discloses all of the claimed elements and their recited relationships. See *Ex parte Masham 2 USPQ 2nd 1647*. Gafni teaches an apparatus with sensors for measuring impedance and temperature (column 15, lines 24-32 of Gafni) and a means for effecting tissue temperature (column 7, lines 54-62 of Gafni). It is noted that the

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limitation "for differentiating in a given area of tissue a tumorous tissue from a normal tissue" is merely "intended use" language, which cannot be relied upon to define over Sliwa, since Sliwa discloses all of the claimed elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. It is further noted that the limitation "comparing said measured tissue impedance over at least a portion of the range of tissue temperatures with reference tissue impedance of the normal tissue adapted for tissue differentiation, wherein said reference tissue impedance is measured over said range of tissue temperatures" was not given any patentable weight since the limitation does not add any structural limitation to the apparatus claim. In regard to claim 6, the temperature range includes temperature 36-37°C, which includes 20-38°C. (column 7, lines 54-62 of Gafni). In regard to claims 7-8, a Peltier element is disclosed. (column 9, lines 3-5 of Gafni). In regard to claim 9, temperature sensors are disclosed. (column 7, lines 58-62 of Gafni).

Allowable Subject Matter

8. Claims 16 and 18-30 are allowed.
9. The following is an examiner's statement of reasons for allowance. In regard to claim 16, the prior art does not teach or suggest an apparatus with processing means for analyzing tissue impedance data over the range of tissue temperatures to obtain a first impedance-temperature derivative of the tissue impedance versus tissue temperatures. In regard to claim 20, the prior art does not teach or suggest a method

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including the method step of acquiring tissue impedance data over the range of tissue temperatures to obtain a first impedance-temperature derivative of the tissue impedance versus tissue temperatures and the step of comparing said first impedance-temperature derivative at a tissue temperature of interest with reference first impedance-temperature derivative of the normal tissue at said tissue temperature of interest adapted for tissue differentiation.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

10. Applicant's arguments filed 4/2/2004 have been fully considered but they are not persuasive. The Applicant correctly asserts that the timely filed terminal disclaimer is sufficient to overcome actual or provisional rejections based on a nonstatutory double patenting ground. However, the terminal disclaimer is insufficient to overcome the 102 prior art rejection of claim 1 as being anticipated by U.S. Patent Application Publication 2002/0026127 to Balbierz et al. The Applicant must either amend or cancel claim 1 or argue that the rejection of claim 1 in view of Balbierz was improper. Since the Applicant has not amended or cancelled claim 1 or presented arguments relating to claim 1, the Examiner maintains the rejection as proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on 703-308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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